

# **ANCOTIL<sup>®</sup> Injection**

Flucytosine 1%

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## **Consumer Medicine Information**

### **What is in this leaflet**

This leaflet answers some common questions about Ancotil. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Ancotil against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### **What Ancotil is used for**

This medicine is used to treat:

- fungal or yeast infections in your body, which are also known as candidiasis, cryptococcosis or chromoblastomycosis.

**Ask your doctor if you have any questions about why Ancotil has been prescribed for you.**

Your doctor may have prescribed Ancotil for another purpose.

Ancotil is not addictive.

Ancotil is available only with a doctor's prescription.

## **Before you have Ancotil**

### **When you must not have it**

**Do not have Ancotil if you have an allergy to:**

- any medicine containing flucytosine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives.

**Do not have Ancotil if you know that you do not have any activity of the enzyme dihydropyrimidine dehydrogenase (DPD) (complete DPD deficiency).**

**Do not have this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not breast-feed if you are having this medicine.**

It is not known if the active ingredient in Ancotil passes into breast milk and there is a possibility that your baby may be affected.

**Do not have Ancotil after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, your pharmacist will dispose of it for you.

**Before you start to have it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you have kidney problems.**

Your doctor will discuss the risks and benefits of using Ancotil and the need to monitor your kidney function. The dose of Ancotil may be adjusted according to your kidney function

**Tell your doctor if you have bone marrow depression or a blood disorder.**

Your doctor will discuss the risks and benefits of using Ancotil and the need to monitor your blood picture, kidney and liver function.

**If you have not told your doctor about any of the above, tell them before you use Ancotil.**

## **Taking other medicines**

**Tell your doctor if you are taking any other medicines including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines and Ancotil may interfere with each other.

These include:

- cytostatics
- cytosine arabinoside
- amphotericin B
- phenytoin
- cytarabine

These medicines may be affected by Ancotil or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Ancotil.

## **How Ancotil is given**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

## **How much is administered**

The dose of Ancotil may be different for each person and ranges between 37.5 to 50 mg per kilogram body weight. Your doctor will decide the right dose for you.

## **How is it administered**

Ancotil is administered by slow intravenous infusion for 20 to 40 minutes. If your kidney function is normal this dose is repeated every six hours.

If your kidney function is impaired the intervals between administrations of the doses could vary up to 24 hours. Your doctor will decide the appropriate dosing for you.

## **How long use it**

Your doctor will determine how long Ancotil should be used.

## **While you are using Ancotil**

### **Things you must do**

If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Ancotil.

**Tell any other doctors, dentists and pharmacists who are treating you that you are using Ancotil.**

**If you feel that Ancotil is not helping your condition, tell your doctor or pharmacist.**

**Ask your doctor or pharmacist if you are concerned about the length of time you have been given Ancotil.**

While you are being treated with Ancotil, your doctor will monitor your kidney function, liver function and blood picture.

## **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Ancotil.**

Ancotil helps to clear the fungal or yeast infection, but it may have unwanted side effects in some people.

All medicines may have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- nausea
- vomiting
- diarrhoea
- skin rashes

These side effects are usually mild and do not last long.

**The following are less frequent side effects:**

- fits
- headache
- sleepiness
- dizziness
- blood tests may show changes to your liver or certain factors in your blood.

**Tell your doctor as soon as possible if you notice any of the following:**

- an allergic reaction

If you have an allergic reaction you may experience swelling of eyelids, face, lips, mouth or tongue, sudden wheeziness, chest tightness, lumpy skin rash

- skin inflammation that may lead to severe blistering

- changes in the way your heart beats

**Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell when you are undergoing, or soon after Ancotil treatment.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

## **After having Ancotil**

### **Storage**

Ancotil will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place where the temperature stays below 25°C.

### **Disposal**

Since Ancotil is usually given in a hospital setting your pharmacist will dispose of any left over Ancotil.

## **Product description**

### **What Ancotil looks like**

Ancotil is an isotonic infusion solution containing flucytosine (1%) and 0.805% NaCl. It comes in a 250 mL glass bottle.

## **Ingredients**

Ancotil also contains sodium chloride, trometamol, hydrochloric acid and water for injections.

## **Sponsor**

Ancotil is supplied in Australia by:

iNova Pharmaceuticals (Australia) Pty Limited

ABN: 13 617 871 539

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